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Docket No.: 025444.1132-US01  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Melton B. Affrime et al.

Application No.: 09/760,588

Group Art Unit: 1614

Filed: January 16, 2001

Examiner: D. A. Jagoe

For: TREATING ALLERGIC AND  
INFLAMMATORY CONDITIONS

**TRANSMITTAL LETTER**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Enclosed are the following items for filing in connection with the above-referenced Patent Application:

1. Interview Summary Letter and
2. Return receipt postcard.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 50-0740, under Docket No. 025444.1132-US01. A duplicate copy of this paper is enclosed.

It is not believed that extensions of time fees are required beyond those that may otherwise be provided for in documents accompanying this paper. However, if additional extensions of time are necessary to prevent abandonment of this application, then such

extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor are hereby authorized to be charged to our Deposit Account No. 50-0740.

Dated: October 31, 2006

Respectfully submitted,

By 

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October 31, 2006

## VIA HAND DELIVERY

Examiner Donna Jagoe  
Art Unit 1614  
United States Patent and Trademark Office  
Remsen Building  
400 Dulany Street  
Alexandria, Virginia

Re: In re United States Patent Application of  
Melton B. Affrime, et al.  
Application No.: 09/760,588  
Filed: January 16, 2001  
For: TREATING ALLERGIC AND  
INFLAMMATORY CONDITIONS  
Art Unit: 1614  
Examiner: D. Jagoe

Dear Examiner Jagoe:

On behalf of my client, Schering Corporation, assignee of the above-referenced application, I submit this letter to record the substance of our personal interview on October 13, 2006 concerning the application. Once again, we appreciate the courtesy that you and Examiner Marschel extended at that interview.

In addition to you and Examiner Marschel, Henry Hadad and I were present at the interview. Mr. Hadad is a Vice President of Schering Corporation.

As reflected in your Interview Summary Report (copy attached), we discussed two topics. First, Examiner Marschel explained the basis for the Notice of Non-Compliant Appeal Brief mailed on October 4, 2006. He explained that there was a risk that the Board of Patent Appeals and Interferences would reject the brief because it did not appear that citations were provided in connection with each claim identifying the location in the application for the support for that claim. He suggested that delay of the appeal would be avoided if the description of each claim in the brief were to include a

Examiner Donna Jagoe  
October 31, 2006  
Page 2

citation to the support in the application for the claim. In order to help expedite the appeal, we agreed to submit an amended brief as Examiner Marschel had suggested.

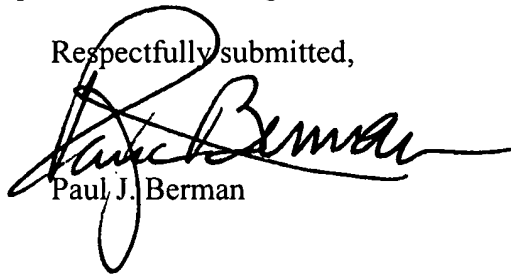
Second, we discussed the patentability of the claims in light of United States Patent No. 6,100,274, issued to Kou, and co-owned by Schering with the present application. You and Examiner Marschel reiterated the position in the June 16, 2005 Office Action that the claims should be rejected under 35 U.S.C. §102(e) because the applicant had not distinguished the method for administering desloratadine claimed in the application from methods disclosed in the '274 patent. We observed that the '274 patent does not recite either a steady state pharmacokinetic profile for desloratadine or the time period of administration of desloratadine to target or achieve a steady state pharmacokinetic profile.

In response, you observed that some of the pending claims recite a specific time period for administration of desloratadine, while others do not. You further observed that in our appeal brief we had grouped all of the pending claims together for purposes of the appeal. You suggested that, if we submit an amended appeal brief in response to the October 4 Notice, we consider grouping the claims that recite a time period separately from the claims that do not recite a time period.

Thank you once again for your time and consideration.

Please contact me if there are any questions concerning this matter.

Respectfully submitted,



Paul J. Berman



### Interview Summary

Application No.

09/760,588

Applicant(s)

AFFRIME ET AL.

Examiner

Donna Jagoe

Art Unit

1614

All participants (applicant, applicant's representative, PTO personnel):

(1) Donna Jagoe.

(3) Paul Berman.

(2) Ardin Marschel.

(4) Henry Hadad.

Date of Interview: 13 October 2006.

Type: a) ☐ Telephonic b) ☐ Video Conference

c) ☒ Personal [copy given to: 1) ☐ applicant 2) ☒ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☒ No.

If Yes, brief description: \_\_\_\_\_.

Claim(s) discussed: 69-84.

Identification of prior art discussed: Kou U.S. Pat. No. 6,100,274.

Agreement with respect to the claims f) ☐ was reached. g) ☐ was not reached. h) ☒ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: See Continuation Sheet.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

  
Examiner's signature, if required

## Summary of Record of Interview Requirements

### Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

### Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

### 37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,  
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

### Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Discussed the reason for the defective Brief, in that there is not enough detail as far as page and line number in the Brief. The office action dated June 16, 2005 makes a 102(e) rejection over Kou because Applicant has not distinguished the claimed method from that of the prior art. There is no manipulative difference between Kou and the claims. Arguments drawn to the chronic nature of the administration of the agent to achieve steady state pharmacokinetics is not reflected in the instant claims.